



“Not in a Month Without an ‘R’ in its Name”: An Historical Overview of 20th Century Seafood Regulation With a Glimpse of the Challenges at the Beginning of the 21st

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“Not in a Month Without an ‘R’ in its Name”:

An Historical Overview of 20th Century Seafood Regulation

With a Glimpse of the Challenges at the Beginning of the 21st

Even the occasional consumer of an oyster on the half shell has probably heard the admonition, “Don’t eat oysters in a month without an ‘R’ in its name.”¹ If one goes to any oyster bar along the any American coast, one can find both those who hold religiously and superstitiously to this warning and those who scoff at it as an outdated and irrelevant. Indeed, some restaurants will not even serve raw oysters during the summer months (May, June, July and August are the months without an R in their names for those without a calendar on hand). Meanwhile, somewhat nervous and uncertain tourists can be seen enjoying a rare opportunity to partake of a dozen or so in the heat of a July or August afternoon wondering if and when they will get the “golden oyster.”² So, what is the truth about oysters? Do the locals possess some ancient wisdom passed down through the generations? Are those souls brave enough to ‘slurp’ a dozen on a Fourth of July vacation really cheating death? The real answers in this case most certainly lie not only somewhere between the two extremes but also beyond this measure of safety.

The more important questions discussed within concern the extent to which seafood safety means something more than the situation described above. What are the health and safety challenges for the seafood industry and how can the American seafood supply be protected? What role do the state and federal governments play? Is consumer knowledge and awareness of risks sufficient, and if so, what does the above confusion imply about the state of that knowledge? What follows is a discussion of the seafood industry, issues of

¹<http://carolinareporter.sc.edu/archive%204-12-20/oyster.html>

²“Golden oyster” is actually a term the author and his friends use to refer to that one oyster among the many they eat which they are convinced will be the cause of their demise, or will at least induce a severely upset stomach.

health and safety in seafood consumption, and attempts to regulate the industry to protect the consuming public all cast in the historical perspective of the development of American seafood and shellfish regulation. While issues confronting the entire seafood industry are addressed, the primary focus herein is directed at the shellfish industry with particular attention given to the consumption of raw shellfish such as oysters on the half shell.

Part I of this article introduces the American seafood and shellfish industry and provides some background data on the composition of the market as well as consumption patterns in the United States. Consideration is given not only to the domestic commercial supply, but also to a significant import segment of the market as well as recreational fishing and harvesting.

Part II addresses the various risks to seafood and shellfish consumers. Again, though risks across the entire industry are addressed, particular attention is given to those risks specific to the shellfish industry. The risks discussed range from those inherent to different types of seafood to health hazards of purely human origin. Both the level of threat and the seriousness of these different health hazards are presented and analyzed. Current means of risk identification and reduction are examined briefly throughout this section.

Part III begins a more specific examination of past attempts at health and safety regulation of the shellfish industry. This portion of the article provides the historical context of current shellfish safety programs while documenting the development and ultimate demise of previous attempts at industry regulation. The section begins with the creation of the National Shellfish Sanitation Program (NSSP) in 1925 and continues through its merger into the International Shellfish Sanitation Conference in 1998. Along the way, several safety issues are introduced that continue to present serious challenges to present efforts to regulate the seafood and shellfish industries.

Part IV addresses the existing regulatory regime in the seafood and shellfish industries. While particular attention is given to the HACCP program instituted by the Food and Drug Administration, other exist-

ing programs such as that run by the National Marine Fisheries Service under the National Oceanic and Atmospheric Administration are also addressed. The current status and vitality of the National Shellfish Sanitation Program, now over 75 years old, is also considered.

In Part V, recent criticisms of the existing regulatory regime are addressed. Inadequacies of the current system are discussed along with potential overlap and duplication among the various programs in existence. The primary focus of this portion of the article is directed toward the recent reports issued by the General Accounting Office in January and July 2001.

The article concludes in Part VI with a prospective consideration of the safety issues facing the seafood and shellfish industry. The General Accounting Office recommendations are considered in light of the historical basis for the current system. Possible alternative approaches to providing for the safety of seafood and shellfish consumers are discussed, and finally, the article ends with a brief consideration of some recurring themes within health and safety regulation in the seafood and shellfish industries.

Part I

For many, seafood is a delicacy. Especially for those from the heartland where fresh seafood is rare, it may be a treat enjoyed only on special occasions or vacations to coastal areas.³ For others, those who live in those coastal areas, seafood is a staple. In truth, this description is becoming more stereotype than truth.

³The author, having grown up in rural Tennessee where seafood rarely means more than fried catfish, enjoyed a somewhat similar experience. His family still celebrates on Christmas Eve with an annual feast consisting of several pounds of shrimp and scallops. Vacations were eagerly anticipated as much for the food as for the actual visits to the beach.

While it may have held true in the past, seafood has become an integral part of the American diet. Fish, in particular, have become a substantial part of a healthy diet, replacing red meats that are increasingly understood to be linked to heart disease and other health threats.

Since about 1980, a shift has occurred in the diets of health-conscious consumers who have increased their seafood consumption. While per capita seafood consumption in the United States remained practically unchanged between 1910 and 1980 at approximately 10-12 pounds per year, that number jumped dramatically over the next few years reaching 15 pounds per capita by 1986 and peaking at over 16 pounds in 1987.⁴ While the rate of growth in the seafood market has leveled off in the last decade, that average American currently eats approximately 20 pounds of seafood per year.⁵ The seafood market itself can be divided into finfish and shellfish. While finfish are consumed in much larger amounts, shellfish consumption is estimated at between 15% and 20% of all annual seafood consumption.⁶ These numbers may still pale in comparison to the per capita 60 pounds of chicken and 80 pounds of beef eaten every year, but the seafood market is the fastest growing of the three.⁷

The reasons for this growth in the seafood industry can, in large part, be attributed to the potential health benefits of a diet high in seafood. Medical research has linked fish consumption to lower risks of heart disease and strokes.⁸ Another explanation for the growth of the market is connected to greater availability thanks to better delivery and preservation methods. Regardless of the explanation, however, seafood consumption is on the rise, and as has been noted, the result is that, especially if the seafood consumer is a more health-conscious consumer, concerns about the safety of the seafood supply are also increasing in importance.⁹

In order to understand many of the safety concerns within the seafood industry, it is important to understand

⁴2-10

⁵3-8; 25-37 Though the total consumption numbers may have been holding steady for the last decade, when recreational fishing consumption is taken into account, it appears that the actual consumption numbers hover around 20 pounds per year. Book 24

⁶Book 24 again

⁷24-188

⁸2-10 again

⁹Book again 22

the composition of the seafood industry itself. Seafood comes primarily from three sources. The first of these is the imported seafood market. Imported seafood accounts for approximately 60% of all seafood eaten in the United States.¹⁰ While meat and poultry supplies are primarily domestic, the United States seafood supply has not been equal to the growing demand. The majority of these imports come from a few countries (Canada, Thailand, China, Ecuador, and Chile), but as many as 160 different countries supply seafood to United States customers.¹¹ Domestic seafood supply can be divided into two categories: commercial and recreational. The commercial market, that which is primarily regulated by the federal and state governments, consists of approximately 4000 processors and distributors for over 250,000 fishermen and a fleet of almost 100,000 vessels.¹² The recreational seafood supply is far less regulated, and thus, far less is known about it. However, it is estimated that over 17 million recreational fishermen supply 10% of the seafood eaten in the United States.¹³

As noted above, consumption patterns for shellfish make up a significant minority of the overall seafood market. Shellfish come from all three sources (imports, domestic commercial and domestic recreational), but unlike the finfish market, the majority of shellfish are produced by the domestic commercial industry.¹⁴ Though any country can export shellfish to the United States, special permits are required before countries can supply the American market for uncooked shellfish. Only four countries, Canada, Chile, Korea, and New Zealand, have agreements with the Food and Drug Administration that permit them to export fresh and uncooked shellfish to the United States.¹⁵

Though the United States market for seafood has grown overall, significant harm has been done to the shellfish industry by several high-profile incidents involving shellfish contamination. The most significant

¹⁰23-12

¹¹3-8 again

¹²Book 22 again

¹³Book again 24

¹⁴4-5

¹⁵4-5

of these centers on Gulf oysters. Louisiana is the top producer of oysters for the country, delivering about 60% of the national oyster harvest, or approximately 170 million oysters annually.¹⁶ Increased concerns about safety since the late 1980's has led to a dramatic drop in demand that threatens the entire Gulf oyster industry. During the period of 1991 to 1996, oyster prices plummeted by 35-40%.¹⁷ Though federal and state governments along with the shellfish industry have attempted to respond to safety concerns with improved safety measures and more effective education of consumers, the industry has not been able to recover. As one fisheries economist stated, "the industry has lost a segment of the population and it will not come back."¹⁸ However, despite the damage done to the Gulf Oyster market, consumers appear to be eating more shellfish each year. A large part of the Gulf Oyster market has been replaced with substitute oysters from other regions such as Washington.¹⁹ Overall, shellfish are and will continue to be a major part of the American diet.

One final fact about shellfish consumption that is essential to any discussion of seafood safety is the fact that shellfish are distinct from most other types of meat in one very important way. Shellfish are very often eaten raw. This aspect of shellfish consumption is a primary contributor to approximately 85% of all seafood-related illnesses.²⁰ Of course, as any true oyster lover can confirm, cooking them ruins both the experience and the taste.

Part II

Seafood Safety

¹⁶15-A6

¹⁷15-A1

¹⁸15-A6

¹⁹15A6

²⁰26-55

The term “seafood safety” encompasses a broad range of issues. There is no one health and safety threat from seafood. Rather, there exists a range of threats, some known and some relatively unknown. Any examination of the health risks posed by seafood is thus incomplete. It is, however, possible to examine some of the more prominent threats in both finfish and shellfish.

The primary areas of risk in the seafood market can be divided into two broad fields: naturally-occurring and human-induced. While the lines between these categories blur at points (for instance, where the same contaminants result from both naturally-occurring and human sources or where human behavior can alter the seriousness of a naturally-occurring health hazard), they still serve as significant dividing lines between two broad groups of risks. Naturally occurring risks can further be divided into seafood toxins and microbial threats, both viral and bacterial. Human-induced risks include both (1) viral and bacterial contaminants that result primarily from sewage dumping and (2) chemical contaminants resulting from industrial or individual pollution of the environment.

Documented seafood-related illnesses affect over 110,000 people per year.²¹ Unreported cases of mild gastroenteritis are probably far more common, but statistics on those illnesses not treated or properly identified are obviously not available.²² The most common illnesses are of the Norwalk Virus variety, which is blamed for between 80 and 90% of the overall total. Natural fish toxins such as Ciguatera and Scombrotoxic Poisoning make up another 10% of the total seafood-related illnesses annually while a host of other causes are the source of the remainder.

While seafood health risks are perhaps less publicized than E. Coli and Salmonella outbreaks in red meat and chicken, they certainly do not pose less risk to the consumer. Indeed, the smaller number of seafood-related

²¹16-18

²²Gastroenteritis is a generic term meaning inflammation of the stomach lining which is applied to the gut-wrenching group of illnesses of many different sources often referred to simply as “food poisoning” or mistakenly as the non-existent “24-hour bug.” Symptoms generally include nausea, diarrhea, and abdominal pain. *CancerWeb Online Medical Dictionary*, available online at <http://cancerweb.ncl.ac.uk/cgi-bin/omd?query=gastroenteritis&action=Search+OMD>.

illnesses has more to do with differences in levels of consumption than it does with actual risk. As noted above, American consumers eat about three times more chicken than they do seafood. In comparison to all seafood, chicken does actually cause more illnesses per pound consumed.²³ This is because the vast majority of seafood consumed is of the safer finfish variety. However, when chicken is compared to shellfish on a pound for pound basis, shellfish pose overwhelmingly greater health risks. In fact, the numbers are shocking. Raw shellfish cause illnesses at a rate more than 100 times greater than that of chicken.²⁴ While chicken causes illnesses in about one out of every 25,000 servings, shellfish illnesses occur in one of each 250 servings. In fact, to put this another way, if American consumers ate as much raw shellfish each year as they do chicken, shellfish-related illnesses would number between 300 and 400 million annually!²⁵

Though the majority of these illnesses are often quite minor, the overall costs to the American consumer are quite substantial. Even at current rates of consumption, seafood-related illnesses exact a heavy cost of society. In fact, 1995 Food and Drug Administration estimates place the cost of shellfish-related illnesses alone at over \$200 million annually.²⁶

Distinct from these calculated reports of seafood illnesses each year are chemical contaminants. Chemical contamination risk levels and their eventual costs to society are largely unknown. Significantly, while most microbial and toxic causes of illnesses produce results almost immediately almost immediately upon contact with the consumer, the length of time and the level of exposure required to cause illness from chemical contamination may be far greater. The information herein is intended only as an introduction to several of the more prominent health risks caused by chemical contamination. Anything further would require far more

²³25-113 Illnesses caused by chicken occur at a rate 8 to 10 times greater than by all seafood combined.

²⁴25-114

²⁵25-114; *see also PoultryNet*, available online at <http://poultrynet.gatech.edu/statistics/States/PerCapitaConsumption.asp>

²⁶4-5

detail than is possible in this overview, and to quote the Committee on Evaluation of the Safety of Fishery Products, “(t)here is no area...that poses greater challenges to both the scientific tools for understanding likely health hazards and the social tools for managing risks, than the diverse collection of chemical residues that find their way into the human diet...”²⁷

Chemical contaminants come primarily in two forms: heavy metals and organic compounds. The most prominent health hazard among these is mercury. Among organic compounds, PCB’s, pesticides and dioxins are the most well-known threats. All of these are of significant concern in seafood because of bioaccumulation. Fish and shellfish accumulate and concentrate contaminants at far higher levels than other food products such as plants and land animals. This phenomenon will be discussed in greater detail below.

Naturally Occurring Health Risks

Among naturally occurring fish toxins, two account for the majority of illnesses among American consumers: Scombroid Poisoning and Ciguatera. Scombroid Poisoning is also known as histamine poisoning, and its symptoms include itching, swelling, and vomiting.²⁸ Scombroid poisoning, resulting from high levels of histamine content in fish, is most common in Mahimahi and Tuna.²⁹ While the symptoms are relatively mild and antihistamine medications can control the effects, Scombroid poisoning affects a total of more than 8,000 Americans in almost every state per year.³⁰ Scombroid poisoning can be prevented with proper refrigeration, because histamine levels increase dramatically in fish that are not relatively quickly after capture.³¹

²⁷Book again 112

²⁸Book again 95

²⁹2-19; Book again 93

³⁰16

³¹Book again 95

Ciguatera is a far smaller risk than Scromboid Poisoning, affecting about 1600 people per year.³² Occurrences of ciguatoxin poisoning are primarily regional. Over 90% of all cases are found in tropical regions including Hawaii, Guam, the Virgin Islands, and Puerto Rico.³³ The toxins result from algae growth in tropical reef areas, and the primary fish species implicated in ciguatera are grouper and red snapper.³⁴ While the risk for consumers is relatively low, the effects of ciguatera can range from those similar to Scromboid Poisoning to death or severe neurological damage.³⁵ Since testing for ciguatoxin is currently not feasible, the only effective means of prevention is to prevent fishing in high-risk areas and limit consumption of high-risk fish.³⁶

Ciguatera and Scromboid Poisoning are the two most common naturally occurring illnesses, but both occur almost exclusively in fish. Shellfish present their own host of natural hazards. Some of these are relatively rare but present quite serious health hazards. Others are far more common but result in only a few life-threatening illnesses. Not all naturally occurring health threats are understood or possibly even known at present, and new risks are currently being researched.

Paralytic shellfish poisoning is one of a group of illnesses that are result from the consumption of shellfish that have been feeding on toxic dinoflagellate organisms.³⁷ The illness is relatively rare and appears to afflict only about 20-30 victims per year.³⁸ It is suspected that, as with most food-borne illnesses, mild cases of paralytic shellfish poisoning are underreported. Poisoning, in its most serious form, can be quite dangerous and even life threatening. The toxin implicated in paralytic shellfish poisoning is saxitoxin, and it causes paralysis of the respiratory muscles, which can result in death by asphyxiation.³⁹ Other symptoms include tingling, burning and numbness as well as drowsiness and incoherence.⁴⁰ At present, there is no treatment or

³²16 again

³³26-166

³⁴Book again 89

³⁵Book again 89-90

³⁶Book again 92-93

³⁷26-167

³⁸Book again 96-97

³⁹26-168

⁴⁰Book again 96-97

antidote for the poisoning. As indicated above, the toxins that cause paralytic shellfish poisoning are result when shellfish consume toxic dinoflagellates. Those organisms are found primarily in “blooms” that occur during the summer months, and the only means of prevention is to close contaminated harvest areas.⁴¹ As a result, very few cases result from commercial shellfish harvesting. Most cases of paralytic shellfish poisoning occur as a result of unauthorized recreational harvesting in closed areas.⁴²

Other shellfish-related illnesses also result from toxic blooms. These are far less common and not fully understood at present. The most significant among these are neurotoxic shellfish poisoning and amnesic shellfish poisoning. Neurotoxic shellfish poisoning occurs in shellfish that have fed on the organisms that cause red tides.⁴³ Red tides occur primarily along the Gulf Coast and Florida’s Atlantic Coast, but one of the most serious outbreaks of neurotoxic shellfish poisoning occurred in North Carolina.⁴⁴ While the illness is not typically fatal, the symptoms are quite similar to paralytic shellfish poisoning in that the nervous system is most seriously impacted.⁴⁵ Amnesic shellfish poisoning has only been identified in the last fifteen years. The first known occurrence of the syndrome took place in Canada in late 1988 and affected over 100 people.⁴⁶ The illness is caused by domoic acid, and leads to disorientation and short-term memory loss as well as death in elderly victims.⁴⁷ Amnesic shellfish poisoning has been quite rare in the United States, but it was recently implicated in the deaths of more than twenty dolphins off the coast of California.⁴⁸

By far, the most common naturally occurring health hazards in shellfish are the *Vibrio* family of bacteria. While the occurrence of *Vibrio*-related illness is relatively low, *Vibrio* bacteria are actually incredibly common—primarily in oysters but also in clams and crab. In fact, one of the most dangerous *Vibrio* types,

⁴¹Book again 98

⁴²2-20

⁴³Book 99

⁴⁴Book 99

⁴⁵Book 99

⁴⁶Book 101

⁴⁷26-168

⁴⁸Andrew Bridges, Naturally Occurring Toxin Suspected in Deaths of 22 Dolphins in Southern California 3-23-2002 wire.ap.org

Vibrio vulnificus, is present in all oysters in the Gulf of Mexico during the months of May to October.⁴⁹ Though *Vulnificus* is a particularly potent bacterium that is common to all coastal waters, only about twenty people per year are sickened by it.⁵⁰ The bacterium does not seem to have a detrimental effect on most healthy consumers. It is, however, extremely dangerous to those with already-weakened livers. Persons with hepatitis, cirrhosis, and similar illnesses are highly susceptible to infections caused by *Vulnificus*. The infection, septicemia, has a mortality rate of over 50% making *Vulnificus* illnesses rare yet extremely dangerous.⁵¹ *Vulnificus* was first documented in 1979, but its dangerous reputation has probably been in existence as long as people have eaten raw oysters. In fact, it is likely that *Vulnificus* is the primary source of the adage that one should not eat oysters in a month without the letter R in its name. *Vulnificus* levels are highest, and thus most dangerous, in oysters taken from warm waters. As a result, almost all cases of *Vulnificus*-caused illness can be traced to raw oysters harvested in Louisiana, Texas, and Florida during the warmer summer months.⁵² The bacterium is also one of the most costly in terms of financial harm. The FDA estimates that *Vulnificus*-related illnesses cost over \$120 million annually, or about 60% of the total cost of shellfish-related illnesses each year.⁵³ It cannot be identified by sight, smell, or taste, so a range of alternative solutions has been proposed to prevent *Vulnificus* illnesses. The most effective means of preventing illness would be to cook all oysters, as the bacterium does not survive thorough preparation.⁵⁴ Since the raw oyster consuming public is unlikely to adopt this approach, other possible methods of prevention center on refrigeration after harvest and restrictions on harvest in warm water. Both methods are extremely costly and thus, extremely unpopular within the oyster industry.⁵⁵

Other forms of *Vibrio* that pose a risk of illness in consumers include *Vibrio cholerae* and *Vibrio para-*

⁴⁹14-F6

⁵⁰4-6

⁵¹4-6

⁵²4-6

⁵³4-6

⁵⁴15-A14

⁵⁵15-A14

haemolyticus. Both are more prevalent than *Vulnificus*, but neither proves as harmful to consumers. The illnesses caused by these two strains of *Vibrio* bacteria are normally limited to diarrhea and nausea, though especially susceptible consumers (again, those with pre-existing liver illnesses) can be affected far more seriously.⁵⁶ These strains of *Vibrio* are also destroyed by thorough cooking and afflict primarily consumers of raw oysters.

Human-Induced Health Risks

Illnesses associated with human activity are far more common than those caused by naturally occurring risks. Shellfish are filter feeders, meaning they gather their food by filtering the water in which they live. As a result, they retain many of the contaminants that pollute their habitat at much higher rates than other types of marine life. The types of human pollution can be most easily separated into two categories. The first type of human pollution is fecal waste contamination, which leads to several viral health threats. The second includes various types of chemical contamination, chief among these being mercury, the complete risks of which are far less understood.

Human fecal waste can contain any of more than 100 different viruses.⁵⁷ Viruses from this rather unsavory source make their way into shellfish through direct dumping from land-based sources, runoff from points inland, and direct dumping by marine vessels. These viruses range from the relatively harmless, such as the Norwalk Virus to the exceptionally dangerous and even life-threatening Hepatitis A virus.⁵⁸ As with many other raw shellfish-associated illnesses, if consumers fully cooked the shellfish before eating them, the viral contaminants and ensuing illnesses could almost always be eliminated.

⁵⁶Book 37-40

⁵⁷Book 49

⁵⁸Book 49

Hepatitis A caused by seafood consumption makes up a relatively small portion of the total number of Hepatitis A cases annually, yet it poses a significant threat when shellfish growing waters are contaminated. In total, Hepatitis A cases connected to seafood and shellfish total approximately 1,000 per year.⁵⁹ Most of these are actually unconnected to the sanitation of shellfish growing waters, however, and are actually due to poor food handling or contamination in food preparation. In fact, the most recent confirmed outbreak of Hepatitis A directly linked to shellfish (raw oysters) took place in 1988 and infected 61 people throughout the southeast.⁶⁰

Norwalk viruses are far less dangerous than Hepatitis A, but they are also far more common. In fact, aside from the common cold, the Norwalk Virus is the largest source of illnesses in the United States.⁶¹ In the context of seafood-related illnesses, the Norwalk virus (actually a family of many viruses) causes over 100,000 illnesses per year.⁶² The illnesses are typically associated with nausea, diarrhea, and abdominal pain and pass within one to two days.⁶³ Norwalk Viruses are a major problem in raw shellfish and are often caused by contamination of shellfish growing waters. In fact, many cases can be connected to shellfish harvesters themselves. An outbreak in 1997 was directly linked to an oysterman in Louisiana who dumped his sewage into the waters in which he was working and thus caused at least 432 people to contract the illness.⁶⁴ Many of these illnesses are preventable through elimination of just such events as well as effective policing of identified contaminated areas.

Chemical contamination often cannot be connected to specific outbreaks of illnesses in the way viral and natural illnesses can.⁶⁵ In fact, for many chemical contaminants any assertion beyond that they are present in seafood is not easily made. The fact that they are present (and there is ample evidence in that regard)

⁵⁹16-18

⁶⁰*About Hepatitis A*, available online at <http://www.about-hepatitis.com/page5.htm>

⁶¹*FDA Bad Bug Book*, available online at <http://vm.cfsan.fda.gov/~mow/chap34.html>

⁶²16-18

⁶³*FDA Bad Bug Book* again

⁶⁴16-18 The oysterman himself was suffering from the virus at the time.

⁶⁵The Japanese “Minimata Disease” incident, which is discussed below at p.XXXXX, is exceptional in that regard.

and that they are present in seafood in far greater quantities than in other food sources, is beyond question and is a matter of substantial concern. The overall risks of chemical contamination are largely unknown, and certainly, they are often dependent on the long-term consumption of contaminated foods. Seafood consumers, however, are far more likely than others to be exposed to potentially harmful chemical contaminants. Fish are contaminated at a higher rate than any other type of food. FDA analysis has determined that over 5% of all fish contain illegal residues and toxins.⁶⁶ The average for all food types is a much lower 2.9 percent.⁶⁷ The various chemical contaminants found in seafood include heavy metals such as mercury and organic compounds such as polychlorinated biphenyls (PCB's), dioxins and a long list of pesticides. These contaminants are a problem in both shellfish and finfish.

While mercury contamination in seafood has probably received the most attention (and does below in this article, as well), other contaminants may be more common and even more threatening. Disturbingly, a 1987 FDA sampling of domestic seafood identified pesticide residues in 73% of all samples.⁶⁸ The health threats of many of these pesticides are unknown. Some pesticides such as DDT are well-known and considered dangerous to consumers.⁶⁹ Others, such as toxaphene are common in the United States yet their health risks are suspected but unconfirmed.⁷⁰ Most pesticides make their way into water from agricultural runoff or direct spraying of coastal lands. They are then concentrated in aquatic life and work their way up the food chain into seafood that is later consumed.⁷¹

PCB's are a significant health threat in seafood. Though they have been banned in the United States since 1977, they still show up in significant concentrations in both fresh and saltwater seafood.⁷² The health risks of PCB's in seafood have also been documented in greater detail than is the case with pesticides. Quincy

⁶⁶25-55

⁶⁷25-55

⁶⁸25-56

⁶⁹In fact, DDT has been banned in the United States since 1972. Book again 120.

⁷⁰Book 121

⁷¹25-55

⁷²25-57

Bay in Massachusetts was at one time the source of great controversy in the national discussion of PCB's. In 1988, it even became part of the national presidential debate.⁷³ The level of PCB's found in lobsters taken from Quincy Bay was so dramatically high, up to thirty times the federal limit of 2 parts per million, that the EPA even recommended that they should not be eaten at all.⁷⁴ To compare PCB risks to those of other food-related health threats, one who consumed Quincy Bay flounder was ten times more likely to develop cancer than those who drank milk, ate peanut butter, or drank diet soda with saccharin.⁷⁵ PCB contaminated waters have often been declared off-limits to fishermen, but the problems of contaminated seafood reach American consumers persists. As recently as 1999, it was discovered that fishermen had been catching fish from the Hudson River in the George Washington Bridge area and selling them to prominent restaurants in the New York region.⁷⁶

Heavy metal, specifically mercury, levels in fish and shellfish are probably the single hottest topic in seafood safety. Other metals, such as lead and cadmium, are also prevalent in seafood. Cadmium, in particular is a significant risk in shellfish as they concentrate the metal at high levels when it exists in their environment.⁷⁷ Still, mercury has received the most attention and has generated the highest levels of concern over the years. All of these metals are toxic to humans and pose substantial risks to pregnant and nursing mothers in particular.

Mercury is most common in seafood in the form known as methyl mercury.⁷⁸ Although mercury exists naturally in the environment, this form, which is toxic to humans, is also created through industrial pollution

⁷³24-87

⁷⁴24-87 A debate ensued with the FDA releasing its own studies that found the actual health threat to be far less severe since most consumers do not eat enough of the seafood to be affected.

⁷⁵25-58 The other activities mentioned in comparison involve food consumption that poses cancer risks to consumers. Peanut butter and milk both contain aflatoxin and cause cancer at 1 in 25,000 and 1 in 100,000 rates respectively (for consumption patterns of four tablespoons and one pint daily respectively). Diet soda with saccharin also causes cancer at about a 1 in 100,000 rate at a one soda per day consumption level. Peter Hutt Article from 1978.

⁷⁶17-B3 Fishing in that area has been banned for over 25 years, and the fishermen and wholesalers involved were later caught and prosecuted, but the practice certainly continues in many areas in New York and around the Great Lakes where PCB levels are also extremely high.

⁷⁷Book 115

⁷⁸*FDA Consumer Advisory, March 2001, available online at <http://www.cfsan.fda.gov/~acrobat/hgadv1.pdf>*

that makes its way into the water and is then incorporated into aquatic organisms and later concentrated in some types of fish and shellfish.⁷⁹ Two types of seafood are the most likely to concentrate large amounts of methyl mercury in their meat. These are large predator fish and shellfish. The first concentrate mercury in their systems at higher levels due to the fact they live longer and eat other fish and organisms that already concentrate the metal while the second serve as filters in contaminated waters and absorb large amounts of the metal from their environments.⁸⁰ The FDA limit for mercury in fish is 1 part per million. Tilefish, swordfish, shark and king mackerel can possess mercury levels as high as 4.54 parts per million.⁸¹ Of most concern are swordfish and shark, which are among the most popular food fish nationally.⁸²

Methyl mercury poisoning can cause severe neurological disorders and death in its victims.⁸³ The most serious health threat posed by methyl mercury is to pregnant and nursing mothers and their unborn or infant children whose neurological development can be damaged severely by even lower levels of mercury exposure. In fact, the FDA has advised pregnant and nursing mothers to avoid the above four types of fish entirely while it has advised others to limit consumption to approximately twelve ounces per week.⁸⁴ Studies from other countries have shown that even lower levels of mercury exposure can reduce intelligence test scores by seven or eight points.⁸⁵ Such results have prompted other groups to suggest the FDA should go farther in its efforts and issue warnings about many other types of seafood as well. In a report entitled "Brain Food: What Women Should Know About Mercury Contamination in Fish," the Environmental Working Group and U.S. Public Interest Research Group criticized the FDA warnings as insufficient to protect pregnant women and even women of childbearing age.⁸⁶ The other types of seafood that they contend are also serious

⁷⁹ *FDA Advisory, March 2001*, again

⁸⁰ *FDA Consumer Advisory, May 1995*, available online at <http://www.cfsan.fda.gov/~acrobat/hgadv7.pdf>

⁸¹ *FDA Consumer Advisory, May 2001*, available online at <http://www.cfsan.fda.gov/~acrobat/hgadv2.pdf>

⁸² *FDA Advisory, May 2001*, again

⁸³ *FDA Advisory, May 1995*, again

⁸⁴ *FDA Advisory, May 2001*, again

⁸⁵ 21-F5

⁸⁶ 6-1

health risks include canned tuna and oysters taken from the Gulf Coast.⁸⁷ At present, however, pregnant women face unknowns that lead many to simply abstain from all fish.⁸⁸

In sum, the dangers posed by seafood consumption are varied and range from serious to seriously annoying. In the section above, this article has presented only an overview of the different groups of threats facing consumers. Subsequent sections present a more detailed analysis of attempts, and the lack thereof, by federal and state regulatory bodies to address these health risks and inform and protect the American consumer.

Part III Historical Underpinnings of Shellfish Regulation

The National Shellfish Sanitation Program Under the Public Health Service

Shellfish have always been a staple of the North American diet. Therefore, placing a date on the first efforts to regulate seafood and shellfish harvesting and consumption would be impossible. At least as early as 1658, the Dutch Council of New Amsterdam had passed regulations governing the harvesting of oysters from the East River.⁸⁹ At least three of the thirteen English colonies had laws regulating shellfish collection in order to prevent overcollecting and guarantee sustained supply.⁹⁰ Health and safety issues surrounding shellfish

⁸⁷6-1 Oysters, especially those from the Gulf of Mexico, have long been considered a mercury-related health risk with the National Shellfish Sanitation Program studying the issue since the Minimata Disaster in the 1950's. *See infra* p. XXXXX.

⁸⁸21-F5 again

⁸⁹History 371

⁹⁰History 371 (New York (1715), New Jersey (1730) and Rhode Island (1734) all passed such laws.)

consumption are more recent yet still date back to the beginning of the last century.

Near the end of the nineteenth century, shellfish sanitation became a national issue. Several places in the United States as well as European countries had experienced outbreaks of illnesses tied to the consumption of shellfish, primarily raw shellfish.⁹¹ The most serious of these occurred in 1924 in New York, Chicago, and Washington, D.C. A typhoid fever outbreak in those three cities was connected to oysters that had been collected from sewage-polluted waters.⁹² This series of incidents sparked a national outcry that led the individual states, which had traditionally had responsibility for this food safety issue, to request the Surgeon General of the Public Health Service to develop a national system of ensuring the safety of the shellfish supply.⁹³ The Surgeon General's response to calls for control measures to protect the consuming public set the stage for over five decades of seafood and shellfish regulation. In fact, it might be more accurate to say the groundwork put in place in 1925 still shapes such regulation to this day.

On February 19, 1925, the Surgeon General convened a conference in Washington, D.C., that included state and city health authorities, the Public Health Service and its Bureau of Chemistry (which would later become the Food and Drug Administration), the Bureau of Commercial Fisheries (the predecessor of the National Marine Fisheries Service) and representatives of the shellfish industry.⁹⁴ This conference, the first of its kind, endeavored to develop a system of sanitary controls for the harvesting, shipping, and production of shellfish in the United States. The result was a series of resolutions for regulation and governance of the shellfish industry that rested primarily on cooperation between the federal and state governments and voluntary compliance by states and members of the industry. The conference stopped short, however, of elaborating the specific means by which the various participants would achieve the goals expressed in those resolutions.

⁹¹History 371

⁹²History 371

⁹³History 371

⁹⁴History 372

The resolutions included the following five principles governing all aspects of the shellfish industry, from harvest to delivery to the consumer:

1.

The beds on which shellfish are grown must be determined, inspected, and controlled by some official state agency and the U.S. Public Health Service.

2.

The plants in which shellfish are shucked or otherwise prepared or packed by the shipper must be inspected and controlled by some official state agency and the U.S. Public Health Service.

3.

There must be such governmental supervision and such trade organization as will make plain the source of shellfish and will prevent shellfish from one source being substituted for those from another source. This will be chiefly a problem of the individual state.

4.

The methods of shipping must be supervised, inspected, controlled and approved by the proper official federal and state agency.

5.

The product must conform to an established bacterial standard and must meet federal, state, and local laws and regulations relative to salinity, water content, food proportion and conform to the Pure Food Laws standards.⁹⁵

In place of more specific guidelines, the conference established a committee to develop any further guidelines that might prove necessary in ensuring the safety of the shellfish supply.⁹⁶

After this conference, the Surgeon General set out the principles on which a national shellfish program would

⁹⁶History 372

be founded. As can be seen in the Surgeon General's letter of August 12, 1925, expressing these principles, the majority of the responsibility for shellfish regulation and monitoring was left to the states who relied on voluntary industry cooperation while the Public Health Service was focused more on providing information to the states and facilitating cooperation among them rather than directly regulating the shellfish industry.⁹⁷ The guiding principles of the time that provided a limited definition of interstate commerce and broad state autonomy in regulating means of production prior to the New Deal Era are evidenced in the shape the "national" program assumed.

As a means of implementing the goals set forth at the conference, the participants agreed that each state would issue certificates that would serve as operating permits to all shellfish shippers that met sanitary standards.⁹⁸ The Public Health Service would disseminate information on each state's program in what was titled the "Progress Report on Shellfish Sanitation."⁹⁹ This system was soon discarded and the Public Health Service moved to a system of program endorsement whereby it evaluated the effectiveness of each state's program. In order to do this, the Public Health Service developed the "Manual of Recommended Practice for Sanitary Control of the Shellfish Industry" and published a list of all certified shellfish shippers in each state.¹⁰⁰ Thus, the National Shellfish Sanitation Program was born.

⁹⁷History 373 The Surgeon General's letter set forth the following understandings based on the conference:

1. The Public Health Service considers that the responsibility for the sanitary control of the shellfish industry rests chiefly upon the individual states; and that the requisite coordination and uniformity of control may best be achieved by mutual agreement among the states, with the assistance and cooperation of the Public Health Service. . . .
2. In accordance with this principle, it is considered that each producing state is directly responsible for the effective regulation of all production and handling of shellfish within its confines, not merely for the protection of its own citizens, but equally for safeguarding such of its product as goes to other states. . . .
3. In order that each state may have full information concerning the measures carried out in other states, the Public Health Service will undertake systematic surveys of the machinery and efficiency of sanitary control as actually established in each producing state, and will report thereon for the information of the authorities of other states. It is believed that, in addition to furnishing valuable information, these reports will have an important influence in stimulating the development of better sanitary control and in promoting substantial uniformity on a higher plane. The officers of the Public Health Service assigned to this survey work will assist the state agencies in determining their sanitary problems, in formulating plans for adequate sanitary control, and in making actual sanitary surveys as far as practicable.
4. In addition to the above, the Public Health Service will continue to extend the services which it is already rendering, especially in conducting scientific investigations of fundamental importance to control, and in serving as a clearinghouse for the interchange of information and the discussion of policies between state authorities.

⁹⁸History 373

⁹⁹History 373

¹⁰⁰History 374

The National Shellfish Sanitation Program (NSSP), as described above, was founded on state regulation with national technical assistance and relied upon voluntary industry participation. Little has changed over the years. The NSSP still depends upon the voluntary cooperation of all participating members. There have, however, been significant changes to the NSSP, its scope, and its composition since 1925.

The first major changes occurred in the 1940's. As already mentioned, the original vision of the NSSP was very much restricted by the prevailing definition of interstate commerce and the proper role of the federal government in regulating economic activity. Though the NSSP has continued to leave the majority of the responsibility for ensuring safety to states, the evolving understanding of the role played by the federal government certainly appeared in revisions of the NSSP. During the 1940's, in the face of worries about paralytic shellfish poisoning, the NSSP added requirements to address this issue of national concern.¹⁰¹ This was the first expansion of the NSSP beyond simply compiling information to facilitate state programs and interstate shipping of shellfish.

During the 1950's, the NSSP entered a new era of heightened activity. Participants realized greater dialogue was needed concerning new and recurring issues the program was confronting. In response, the first National Conference on Shellfish Sanitation took place in 1954.¹⁰² Though the 1925 Report of Committee on Sanitary Control of the Shellfish Industry in the United States had been revised twice in the ensuing three decades (in 1937 and 1946), participants acknowledged that a more substantial revision had become necessary.¹⁰³ As the Second and Third National Workshops convened in 1956 and 1958, the NSSP was also developing a two-part manual describing the program in greater detail.¹⁰⁴ These manuals, Part I entitled "Sanitation of Shellfish Growing Areas" and Part II entitled "Sanitation of Harvesting and Processing of Shellfish," were published between 1957 and 1959.¹⁰⁵

¹⁰¹History 375

¹⁰²First Conference Citation

¹⁰³History 375

¹⁰⁴History 375

¹⁰⁵History 375

During the same period, new health risks associated with shellfish were presenting themselves. In 1957, evidence demonstrated that shellfish concentrated radioactive materials found in their environment, and health guidelines were added for these contaminants.¹⁰⁶ Research also took place throughout the 1950's concerning the effect of industrial pollution on shellfish. Much of this research was prompted by the occurrence of what came to be known as "Minimata Disease" in Minimata Bay, Japan.¹⁰⁷ Starting in 1953, a severe neurological disorder was identified in the villagers who lived in the vicinity of the Bay and ate large quantities of seafood taken directly from it. This illness attacked the nervous system and caused severe permanent disabilities and degeneration of the tissues of the brain as well as death in many cases.¹⁰⁸ By 1960, the disease had been linked to the Chisso Corporation that was producing vinyl chloride and dumping mercury into the bay.¹⁰⁹ Minimata Disease was, in fact, methyl mercury poisoning, and over 3000 people in a village of approximately 10,000 developed the illness.¹¹⁰ This disaster captured the attention of the American public health community. The Fourth Shellfish Sanitation Workshop addressed the similarities of areas along the Gulf of Mexico with Minimata and studies were conducted into potential health hazards facing the American consuming public.¹¹¹

At the same Workshop in 1961, results of studies were presented that indicated exceptionally high level of metals such as copper and zinc in shellfish taken from the Chesapeake Bay.¹¹² In particular, oysters demonstrated extremely high concentrations of these metals. These results raised serious concerns not only about the safety of oysters containing these metals (as well as other known health hazards such as paralytic shellfish poisoning which had been worrisome since the 1940's), but also raised the question, "What else do shellfish

¹⁰⁶History 375

¹⁰⁷4th Conference- 226

¹⁰⁸4th Conference- 226

¹⁰⁹<http://www.american.edu/TED/MINAMATA.HTM>

¹¹⁰Same website

¹¹¹4th conference 227

¹¹²4th Conference 229

accumulate?”¹¹³ The Workshop participants were unable to answer this question, but it clearly indicated the need for a better understanding of the levels of human contaminants concentrated in the shellfish supply and the risks those posed to consumers.

By the time of the Fifth Workshop in 1964, concerns about shellfish safety had increased significantly. The Public Health Service was taking a much more aggressive stance in pursuing the goals of the NSSP and protecting the American consumer. Much of this new intensity is evidenced in statement of Eugene Jensen, the head of the Shellfish Sanitation Branch of the PHS. Jensen, in his comments at the Workshop, made several recommendations for the continuation of a viable American shellfish industry. He concluded that the coastal development of the post-World War II period had brought the shellfish industry a host of new challenges that were making it “exceedingly difficult to maintain a satisfactory confidence factor in the (shellfish supply).”¹¹⁴ It was the position of the PHS to remain faithful to the principle that shellfish must be as safe as other foods. In order to accomplish that, Jensen suggested the shellfish industry and the state and federal governments faced a major crossroads at which they had to choose whether to allow continued consumption of raw shellfish.¹¹⁵ As alternatives to the existing system and efforts to reduce the risk of raw shellfish consumption, Jensen proposed discouraging consumption of raw shellfish, banning raw shellfish from interstate commerce, and warning consumers of the unavoidable health risks posed by raw shellfish.¹¹⁶ Though Jensen acknowledged that few changes of the nature he proposed were likely, he warned participants that a system accepting the status quo and expecting the NSSP to provide for the safety of the shellfish supply was “rapidly becoming obsolete.”¹¹⁷

One method of shellfish sanitation that was discussed in great detail at the 1964 Workshop and was endorsed

¹¹³4th Conference

¹¹⁴5th Workshop 74

¹¹⁵5th Workshop 72

¹¹⁶5th Workshop 72 (It is interesting to note the similarities of Jensen’s third proposal involving warning consumers of the inherent risk of raw shellfish to the program currently in place.)

¹¹⁷5th Workshop 73

by Jensen was depuration. Depuration is a post-harvest treatment process “in which shellfish are held in a clean water environment for a time sufficient to permit them to free themselves of (many viral and bacterial contaminants) through normal biological processes.”¹¹⁸ Depuration was not considered a viable solution to chemical contamination of shellfish waters but rather was focused primarily on combating human waste contamination and natural health risks.¹¹⁹ Though the depuration process had been in existence since the previous century and used extensively in Europe, very little had been done to bring the process to the United States.¹²⁰ Five states reported on research they were conducting into depuration and its promise in the area of shellfish decontamination. The results were mixed, and given industry sentiment that depuration would add significantly to the costs of the shellfish processing without guaranteeing significantly improved safety, no further action took place.¹²¹

The National Shellfish Sanitation Program Under the FDA

The 1960’s proved an eventful period for the NSSP. Not only did the Program hold three Workshops (1961, 1964 and 1968) and revise the Manual of Operations in 1965, but federal responsibility for the program was also transferred from the Public Health Service to the Food and Drug Administration in 1968.¹²² In shifting responsibility for shellfish safety, the Secretary of Health and Human Services made the FDA the principal federal agency responsible for shellfish regulation.¹²³ The 1960’s had also been a period of increased concern for those involved in the NSSP and working to improve shellfish safety. There existed a growing sense that

¹¹⁸Depuration Plant Design i

¹¹⁹DPD 1

¹²⁰5th workshop 74

¹²¹5th Workshop 2-8

¹²²History 376

¹²³33 Fed Reg 9909 (July 10, 1968)

the NSSP did not and could not meet its goals of providing a safe shellfish supply to consumers. In particular, the federal government was not seen as providing an adequate coordinating structure within which the states and the shellfish industry would protect the shellfish supply.

The primary problem identified with the NSSP was that the Public Health Service, and later the FDA, had only one power in the NSSP—the power to decertify a state’s shellfish sanitation program.¹²⁴ In fact, during the 1950’s this issue had arisen, and the program endorsement system had been criticized because the process by which the PHS made the “program endorsement” decision appeared arbitrary and highly subjective.¹²⁵ As the NSSP entered the 1960’s it set about the process of developing objective criteria for program endorsement. That project resulted in the 1965 revision of the Manual of Operations mentioned above.¹²⁶ This manual on the “Appraisal of State Shellfish Sanitation Programs” laid out several procedures that states could choose to undertake if they wished to be endorsed by the PHS.¹²⁷ Yet, states faced very few, if any, consequences, short of the drastic step of removal of PHS endorsement, if they neglected their role in ensuring shellfish safety. This voluntary system was in place when the FDA was given control of the federal role in the NSSP in 1968.

As the FDA assumed this responsibility, it also examined ways in which the NSSP could be modernized and made more effective. The need for this effort was made clear by the FDA who stated, “(i)t has become evident...that harvesting, processing, packaging, and storage practices in the shellfish industry are in many instances not adequate to assure that consumers receive only safe and wholesome products.”¹²⁸ By 1971, the FDA had begun considering changes to the NSSP, including issuing formal regulations for the program. The need for just such a formal authorization of power was supported by such instances as a 1972 memorandum from the Department of Health and Human Services calling into question the legal

¹²⁴Fed Reg 25919

¹²⁵Fed Reg 25917

¹²⁶Fed Reg 25918

¹²⁷Fed Reg 25918

¹²⁸Fed Reg 25918

status of the NSSP.¹²⁹ This memorandum called into question the power of the FDA to take any action whatsoever under the Food, Drug and Cosmetics Act for noncompliance with the voluntary NSSP.¹³⁰ The GAO further called into question the effectiveness of the NSSP in 1973 when it issued its report “Protecting the Consumer from Potentially Harmful Shellfish” which found the Program woefully inadequate to protect American consumers.¹³¹ The GAO found that:

1.

Shellfish not meeting NSSP standards were reaching the consumer in quantities sufficient to called the effectiveness of the NSSP into question;

2. The FDA was not adequately monitoring the states to ensure shellfish safety;

3. The States were also not fulfilling their responsibility to guarantee the safety and sanitation of shellfish growing waters or processing conditions.¹³²

Among the GAO findings were conclusions that 31% of shellfish sampled did not meet NSSP standards for safety and 40% of shellfish processors operated in unsanitary conditions.¹³³ The Report was also critical of the absence of any standards with regard to toxic metals other than mercury and the failure of the FDA and states to follow-up on contaminated shellfish and identify the source waters from which they were taken.¹³⁴

As the FDA considered what approach to take with regard to improving shellfish safety, one decision made early on was to preserve the framework established five decades earlier by the NSSP. Rather than begin with a clean slate, the FDA opted for designing a program based on the pre-existing NSSP and work to shore up

¹²⁹GAO 1984 6

¹³⁰GAO 1984 6 Indeed, Virginia had gone to the courts seeking relief from an unsatisfactory program rating from the FDA which could have led to decertification.

¹³¹Fed Reg 25918

¹³²Fed Reg 25918

¹³³Fed Reg 25918

¹³⁴Fed Reg 25918

its inadequacies. The primary among these was determined to be the absence of any regulatory framework upon which the NSSP rested. Thus, on June 19, 1975, as the National Shellfish Sanitation Program turned fifty years old, the FDA issued a notice of proposed rule making to create the National Shellfish Safety Program.¹³⁵

The proposed regulations for the National Shellfish Safety Program had been several years in the making and began with the following introduction of purpose:

The Commissioner of Food and Drugs is proposing regulations to ensure the safety and wholesomeness of fresh and frozen molluscan shellfish (oysters, clams and mussels) sold in interstate commerce. The proposal is designed to maintain and strengthen the voluntary 50-year-old National Shellfish Sanitation Program under which the Federal Government, the States and the industry cooperate to ensure safe and wholesome shellfish. The proposed regulations would formalize the procedures under which the existing program has been operating, and make them nationally uniform. They would define the scope, requirements and responsibilities of the State and Federal governmental agencies involved. The proposal is intended to satisfy the needs for procedural and other improvements in the existing shellfish control program. . . .¹³⁶

The NSSP, which had been structurally unchanged since 1925, had failed to keep up with changing times and circumstances. As the FDA stated, improvements in refrigeration and distribution systems had moved the fresh shellfish industry from a regional industry to a national one that required a heightened level of uniform quality control.¹³⁷

The primary issue addressed by the FDA in its proposed regulations was the lack of any real enforcement power by which it could monitor state and industry activity. It concluded that the only power possessed by the FDA, decertification of a state program for failure to meet Program guidelines was “grossly impractical” and “neither serves effectively to ensure that only sanitary shellfish reach the consumer nor does it deal practically with the economic interests of States where the shellfish industry is of great importance.”¹³⁸ The conclusion was that the FDA needed a range of enforcement options that were better tailored to effective

¹³⁵Fed Reg 25916

¹³⁷Fed Reg 25916

¹³⁸Fed Reg 25919

federal enforcement of safety standards. Those enforcement options needed to have real effect as well. The decertification power held by the FDA did not actually prevent the shipment of unsafe shellfish in interstate commerce. In fact, the FDA acknowledged that a decertified state would still be able to ship its shellfish to any person in any state who was willing to accept it.¹³⁹ The FDA also could not take action against individual shippers but had to rely on the states to take action. The FDA had little more than its credibility and a thin power of persuasion with which it was charged to protect shellfish consumers. The consuming public was of much greater focus than had been the case fifty years earlier. As the FDA stated, “Since its inception, the NSSP has played a major role in shellfish sanitation. The NSSP does not, however, bring together all persons interested in this subject. All members of the public are affected by, and many are interested in, the manner in which our consumer goods and resources are regulated. It is important, therefore, to adopt a more formal and public approach to the regulation of the shellfish industry in the United States.”¹⁴⁰

The proposed regulations reforming the NSSP were premised upon on FDA authority under the Federal Food, Drug & Cosmetic Act and left primary enforcement responsibility with the states but allowed the FDA more ability to coordinate and monitor that enforcement. The FDA provided a substantial justification for this formalization of the program. First, it noted the failure of almost one third of the states participating in the NSSP to meet existing standards.¹⁴¹ Further, the FDA pointed out the patchwork of standards that existed across the country. States participating in the NSSP were “simply ignoring” the Manual of Recommended Practices which caused safety and quality to vary widely from state to state.¹⁴² The regulations established uniform national standards for shellfish growing waters, product labeling, and control practices and sanitary requirements of shellfish handlers and processors.¹⁴³ All of this, the FDA proposed to organize under the renamed National Shellfish Safety Program.

¹³⁹Fed Reg 25919

¹⁴⁰Fed Reg 25919

¹⁴¹Fed Reg 25920

¹⁴²Fed Reg 25920

¹⁴³Fed Reg 25920

The ‘new and improved’ NSSP proposal was not received well by the states and industry representatives. The FDA received 274 comments regarding its proposal, and these overwhelmingly argued against the regulations.¹⁴⁴ The primary arguments against the regulations rested on economic burden for enhanced safety measures. The states asserted they had inadequate resources and insufficient support to achieve the new level of enforcement to which the proposed regulations aspired.¹⁴⁵ Industry representatives likewise complained that the changes proposed would place economic hardships upon them unwarranted by the increased measure of safety that would be achieved.

The 9th National Shellfish Sanitation Workshop took place on June 25 and 26, 1975, and focused almost entirely on the proposed regulations. There, FDA representatives attempted to explain the proposed regulations and reiterated the need for what the keynote speaker for the previous year’s workshop, FDA Chief Counsel Peter Barton Hutt, called a more precise “rifle approach” as opposed to the “shotgun” approach that was its only enforcement weapon.¹⁴⁶ The FDA stressed that the proposals were not an attempt by federal regulators simply to expand their power but were in line with needs identified by the GAO and the FDA over the previous five years.¹⁴⁷ The FDA also made it clear that consumer confidence in shellfish safety was essential and that confidence was slipping and would be reinforced by more open procedures that made federal-state-industry cooperation official and assuredly legal.¹⁴⁸ Again however, the Workshop participants focused primarily on the costs of any proposed changes to the NSSP. They also showed concern at the formalization of the program, showing a clear preference for the informal workings of the NSP as it existed. The comments of John Ray Nelson of the Gulf Coast Shellfish Industry made this point outright when he said, “there is very little fundamentally wrong with the proposed regulations as such, but by publishing them in

¹⁴⁴50 Fed Reg 7797 (February 26, 1985)

¹⁴⁵Fed Reg 1985

¹⁴⁶9th Workshop 15

¹⁴⁷9th Workshop 15

¹⁴⁸9th Workshop 15

the Federal Register, they will become law rather than guidelines.”¹⁴⁹

Ultimately, the proposed regulations remained nothing more than a proposal. The period for comment ended in 1975 and little was done to pursue a final rulemaking. The National Shellfish Sanitation Program was left unchanged. Remarkably, the 10th National Shellfish Sanitation Workshop took place in June of 1977, and the tone had changed dramatically. Very little time was spent discussing the proposed FDA regulations. The Chief of the Shellfish Sanitation Branch at the FDA, J. David Clem, did address the workshop and discuss the status of the proposed rulemaking.¹⁵⁰ He acknowledged the delay and silence from the FDA and said a revised proposal was planned but provided no further details on the regulations.¹⁵¹ David Dressel of the National Marine Fisheries Service addressed the workshop and declared that the single greatest problem facing the shellfish industry at that time was overregulation.¹⁵² Little else needed to be said about the proposed regulations. Any plan to give the FDA official authority to oversee shellfish safety had passed away quietly in that two-year period.

Ten years later, on February 26, 1985, the FDA finally officially shut the door on its regulations by withdrawing the proposed rule creating the National Shellfish Safety Program.¹⁵³ In what was almost an afterthought, it cited for this decision the fact that economic analysis had shown the proposed rule would have cost the shellfish industry \$24 million annually and the states an additional \$6.2 million per year.¹⁵⁴ No statement of the cost savings due to increased safety and a reduction in illnesses was provided for comparison. Another possible interpretation is that the FDA regulations were washed away by the anti-regulatory wave that had swept through Washington in the ensuing ten years. The FDA also asserted that it had determined, in an about face from ten years previous, that federal regulations were unnecessary. It cited as the basis for

¹⁴⁹9th Workshop 38

¹⁵⁰10th Workshop 14-15

¹⁵¹10th Workshop 14

¹⁵²10th Workshop 17

¹⁵³Fed Reg 1985 again

¹⁵⁴Fed Reg 1985 again

that surprising switch some recent GAO findings that the regulations would have left significant gaps in the shellfish safety net and the creation of the Interstate Shellfish Sanitation Conference.

Modern Era of Seafood and Shellfish Regulation 1982-Present

Based on the “dirty laundry” the FDA had aired in the preamble to its proposed regulations, it was evident that there existed severe problems of shellfish safety and inaction was not a viable option.¹⁵⁵ The states and industry were certainly not sitting still waiting for FDA rulemaking to proceed. Indeed, along with their direct efforts to prevent rulemaking, they also moved to reshape the NSSP themselves in the hopes of heading off any efforts to federalize the program. The result of these efforts was the creation of the Interstate Shellfish Sanitation Conference (ISSC) in 1982. The ISSC was developed by the states and industry with FDA cooperation between 1979 and 1982.¹⁵⁶ The model used for this voluntary program was the National Conference of Interstate Milk Shippers, which had been in existence since 1950 and was considered by ISSC planners a successful example of national coordination to protect the public health.¹⁵⁷ The ISSC describes its mission as follows:

(T)o foster and promote shellfish sanitation through the cooperation of state and federal control agencies, the shellfish industry, and the academic community. To achieve this purpose the ISSC:

-

Adopts uniform procedures, incorporated into an Interstate Shellfish Sanitation Program, and implemented by all shellfish control agencies;

- Gives state shellfish programs current and comprehensive sanitation guidelines to regulate the harvest-

¹⁵⁵9th Conference 15 Indeed, Workshop participants complained as much about the fact the FDA had revealed the seriousness of the shellfish safety program’s problems in its proposed rulemaking as they did about the proposed regulations themselves!

¹⁵⁶NSSP History again 376

¹⁵⁷NSSP History again 376

ing, processing, and shipping of shellfish;

- Provides a forum for shellfish control agencies, the shellfish industry, and academic community to resolve major issues concerning shellfish sanitation;
- Informs all interested parties of recent developments in shellfish sanitation and other major issues of concern through the use of news media, publications, regional and national meetings, internet, and by working closely with academic institutions and trade associations.¹⁵⁸

Thus, the ISSC organized a uniform national standard for shellfish safety much in the way the FDA had proposed yet in clear rejection of the path of federal regulation.¹⁵⁹ The ISSC made further steps to coordinate federal, state, and industry activities when the FDA entered into a Memorandum of Understanding with the ISSC officially acknowledging the cooperative relationship the two bodies intended to occur.¹⁶⁰

The single largest endeavor undertaken by the ISSC was precisely that proposed by the FDA in 1975, uniformity among the states. As noted above, several states were ignoring the NSSP manual, which the FDA again revised in 1985, and shellfish supply was less safe as a result. The ISSC, working with the FDA, began in 1987 attempts to create a Model Ordinance to be enacted by all states participating in the ISSC.¹⁶¹ The draft Model Ordinance was presented and adopted in 1992.¹⁶² The largest question looming above this process was the role to be played by the existing NSSP Manual. Was it to be discarded or would it co-exist with the new and potentially conflicting rules of the ISSC? In the end, the decision was reached that the NSSP would be incorporated in large part into the Model Ordinance.¹⁶³ The portion of the NSSP Manual that did not fit within the limits of the Model Ordinance was the basis of the Interstate Shellfish

¹⁵⁸ *History of the ISSC*, available online at http://www.issc.org/ISSC/Background/History_ISSC.TEXT.htm

¹⁵⁹ Fed Reg 1985 again

¹⁶⁰ 49 Fed Reg 12751 (March 30, 1984)

¹⁶¹ NSSP History again 379

¹⁶² NSSP History again 379

¹⁶³ NSSP History again 379

Sanitation Program, but in order to prevent confusion, the new program reverted to the title of National Shellfish Sanitation Program.¹⁶⁴ Thus, finally, in 1998, the NSSP was effectively moved under the umbrella of the ISSC. No further workshops have taken place since the creation of the ISSC in 1982. In their stead, the ISSC meets annually to address issues of concern with regard to shellfish safety.

To fully understand the process that took place throughout the 1980's and 1990's and

Continues today, it is essential to back up a bit to 1984 and examine the environment under which the ISSC and other current programs came to be what they are now. 1984 marks the date of the FDA Memorandum of

Understanding with the ISSC as well as the release of the GAO report, Problems in Protecting Consumers from Illegally Harve

The report had been requested by New York Congressman Thomas J. Downey after 750 New Yorkers were sickened by what appeared to be a Norwalk virus they contracted from eating raw clams.¹⁶⁶ The conclusions of this report illustrate the change in political environment that had taken place since 1975.

The GAO found severe problems with the NSSP and with FDA. These findings could not be called surprising as most if not all of them had existed ten years earlier and had been addressed by the FDA as major motivating factors for its proposed regulations. The GAO's conclusion with regard to the NSSP was that "(it) has laudable objective but cannot enforce compliance."¹⁶⁷ The fact that the FDA lacked any enforcement power left it unable to address violations of the program. The GAO went on to address the serious issues at the state level that had also been brought to light in 1975. First, the states had insufficient staff and equipment to control illegal harvesting.¹⁶⁸ Though states bore full responsibility for supervision of shellfish harvesting, the GAO identified immense disparities between resources available and needed to adequately

¹⁶⁴NSSP History again 379-380

¹⁶⁵See *supra* p. XXXXX, text after note 66 for prior reference to these documents. See also GAO 124646, June 14, 1984.

¹⁶⁶GAO 1984 i

¹⁶⁷GAO 6

¹⁶⁸GAO 9

police illegal activity that resulted in the harvesting of contaminated shellfish.¹⁶⁹ Second, the program provided no successful means of identifying the source and original harvester of shellfish.¹⁷⁰ According to the report, and again as had been put forth in 1975, contaminated shellfish, once identified, could not be linked to specific growing waters or harvesters which meant states had no ability to determine the specific causes (contaminated growing areas) for the effects (contaminated shellfish) they were observing.¹⁷¹ Third, the fines imposed on illegal harvesters were inadequate to deter such activity.¹⁷² The standard fines for illegal harvesting were usually about \$25, which meant illegal activity promised an almost guaranteed reward far in excess of any potential penalty.¹⁷³ Finally, growing areas were not being adequately inspected.¹⁷⁴ The report found that contaminated areas were likely still open for harvesting because waters were not regularly inspected. This again pointed out the dangers posed by insufficient resources.

After reaching all of these conclusions, most the very same that had been reached by the FDA in 1975, the GAO came to a very different result. The GAO did not recommend federal regulation to create a coordinated and uniform shellfish safety program. In fact, the GAO said such a program would create an “adversarial relationship” between the FDA and the states, citing state objections to the 1975 proposals as evidence.¹⁷⁵ Instead, the GAO recommended pursuing development of the ISSC as a cooperative program involving the FDA.¹⁷⁶ The report treated the voluntary nature of the program, what had once been a source of criticism, as one of its primary benefits, saying self-imposed requirements would be more effective than outside regulation.¹⁷⁷ The GAO advocated adoption of the program, rejecting central control or federal supervision. This analysis had substantial force at the time. When the FDA withdrew its proposed regulations a year later, it

¹⁶⁹GAO 9

¹⁷⁰GAO 10

¹⁷¹GAO 10

¹⁷²GAO 11

¹⁷³GAO 11

¹⁷⁴GAO 12

¹⁷⁵GAO 16-17

¹⁷⁶GAO 18

¹⁷⁷GAO 18

largely adopted the position of the GAO report.¹⁷⁸

Though federal regulation of the shellfish sanitation program died in the mid-1980s, concerns about seafood and shellfish safety certainly did not. By 1988, Congress was focused on seafood safety and considering means of addressing what were perceived as severe health risks. Heightened concerns about seafood safety was best summed up in the 1988 GAO report, Seafood Safety- Seriousness of Problems and Efforts to Protect Consumers, as a result of the belief seafood posed unacceptable health risks because it was not subjected to mandatory inspections in the way chicken and beef are.¹⁷⁹ The facts that seafood was being consumed in greater quantities than ever before and that seafood posed health risks at least in equal proportion to those posed by chicken and beef made the absence of mandatory inspection even more controversial.¹⁸⁰ Still, Congress did not act to institute mandatory inspection though debate continued through the rest of the decade and into the 1990s.

The status of federal and state seafood safety programs as of 1988 could only be described as scattered. Indeed, federal and state regulation as well as public-private cooperative programs presented a patchwork of oversight that had been instituted at various points in time and had evolved and been reshaped into their current forms (among these the NSSP and ISSC). A more complete listing of the various programs in place at the time included at the federal level: 1) by the FDA: a limited amount of processors plant inspections and product sampling under the Food, Drug and Cosmetic Act, the NSSP, and the Salmon Program—a voluntary harvesting and processing inspection program; 2) by the National Marine Fisheries Service: the Voluntary Seafood Inspection Program offering fee-based inspection and grading of fish and shellfish and Lacey Act enforcement to prevent illegal harvesting of fish and shellfish; and 3) a collection of smaller programs headed by the National Ocean Service, Office of Oceanic and Atmospheric Research, Centers for Disease Control, Fish and Wildlife Service, National Toxicology Program, and an extensive list

¹⁷⁸Fed Reg 1985

¹⁷⁹GAO 1988 11

¹⁸⁰*See supra* notes XXXXX and XXXXX and accompanying text.

of statutory enforcement programs under the Environmental Protection Agency.¹⁸¹ This list only describes federal programs.

At the state and local level, many of the programs mentioned above were duplicated or overlapped by similar inspection programs, and the ISSC ensured that each shellfish producing state at least had responsibility for overseeing a program of shellfish sanitation. Actual cooperation with ISSC standards by the member states (23 in total) was found to be an entirely different story. The FDA surveyed the program in 1985 and 1986 and found that 80% of the states were in violation of growing area and water classification rules, 60-80% were not conforming with patrolling and enforcement requirements, and 70-80% were not meeting plant sanitation standards.¹⁸² Nine states, 40% of the NSSP participants, were considered to be at a level of substantial nonconformance that was of public health significance.¹⁸³ This number was almost identical to that published twenty years earlier indicating that shellfish sanitation efforts were failing or at least having no effect. Despite these results, the GAO concluded that no universal mandatory inspection program was warranted for either seafood or shellfish.¹⁸⁴

Congress was not yet convinced that increased federal involvement was unneeded though it is difficult to say they were moved to action. Multiple committees in the House of Representatives in particular conducted lengthy hearings annually on the status of seafood safety in the United States.¹⁸⁵ A general description of these hearings would include numerous introductory comments by Representatives followed by testimony of representatives from the Food and Drug Association and National Marine Fisheries Service outlining the current status of federal programs. State program representatives as well as industry representatives and members of consumer public interest organizations also made statements at these hearings. As could be

¹⁸¹GAO 1988 32-39 The FDA sampling described above covered less than 1% of the domestic seafood supply. 63

¹⁸²GAO 43-45

¹⁸³GAO 45

¹⁸⁴GAO 65

¹⁸⁵See, e.g., Sources 24 and 25

expected, the views presented varied little from year to year and the hearings ended with gracious thanks to the participants but with no action by the committees. In 1992 testimony before the Senate regarding the Consumer Seafood Safety Act, FDA Commissioner David Kessler placed what was probably the final nail in the coffin of universal mandatory inspection. In his testimony, he presented the Bush Administration's opposition to the bill and conclusion that existing programs were protecting the consuming public and the proposed federal law would create "duplicative regulatory systems" that would fracture the existing amalgam of programs.¹⁸⁶ More importantly, Kessler stated the FDA's preferred course of action, which was to continue with its existing structure while developing an inspection system based on Hazard Analysis and Critical Control Point (HACCP) principles.¹⁸⁷ These HACCP principles have since come to dominate the entire universe of seafood and shellfish regulation.

HACCP in the Seafood and Shellfish Industries

What is HACCP?

Hazard Analysis and Critical Control Point (HACCP) is not so much a program as it is a way of thinking about safety. It is not a new concept, though its implementation in the seafood and shellfish industry dates officially only to the early 1990's. HACCP principles were first developed by the Pillsbury Company in the early 1960's for food intended for the space program as a means of ensuring the safety of food to be eaten by astronauts when adequate testing was impossible.¹⁸⁸ The end goal, safe products available to consumers,

¹⁸⁶Source 23-pp.11-14

¹⁸⁷23-12

¹⁸⁸See *FDA Backgrounder-HACCP: A State-of-the-Art Approach to Food Safety*, October 2001, available online at <http://www.cfsan.fda.gov/~lrd/bghaccp.html>; see also 59 Fed. Reg. 4142, at 4147 (quoting Howard E. Bauman of Pillsbury, "We concluded after extensive evaluation that the only way we could succeed would be to develop a preventive system. This would require us to have control over the raw materials, process, environment, personnel, storage, and distribution as early in the system as we possibly could. We felt certain that if we could establish this type of control, along with appropriate record keeping, we should be able to produce... a product we could say was safe. For all practical purposes, if this system was

is the same under an end-product testing system or a HACCP-based program, but philosophically, the two approaches are “mirror image(s)” of each other.¹⁸⁹

End-product testing and plant inspections, the more traditional approaches to food safety, are reactive rather than preventive as described by the FDA.¹⁹⁰ HACCP principles shift the focus from the end result to the process used to reach that result in order to ensure a safe result in a more efficient manner. HACCP is a process of assessing risk attempting to control it and prevent safety issues rather than reacting to unsafe results. HACCP programs are also unique in that they are designed and implemented by industry participants and thus require a larger degree of private cooperation than more traditional regulatory approached. This does not mean, however, that the FDA is absent from the development of HACCP programs. In fact, the FDA has established a list of seven fundamental principles on which HACCP-based programs are designed:

1.

Analyze hazards- potential hazards and measures to control them are identified;

2. Identify critical control points- find points in the food production process at which hazards can be controlled or eliminated;

3. Establish preventive measures with critical limits for each control point- create standards by which one can determine a risk has been effectively controlled or eliminated (such as a minimum cooking temperature at which microbial contaminants are killed);

4. Establish procedures to monitor the critical control points- create oversight to guarantee hazard control;

5. Establish corrective actions to be taken when monitoring shows that a critical limit has not been met (such as disposal or reprocessing)

implemented correctly, there would be no testing of the finished packaged product other than for monitoring purposes.

¹⁸⁹27-251

¹⁹⁰*FDA Backgrounder*, 1

6. Establish procedures to verify that the system is working properly- check the established system to be sure the standards for hazard control (not hazard control itself) are being met;
7. Establish effective record keeping to document the HACCP system- record hazards and control methods as well as performance of hazard control system.¹⁹¹

The one step not found in the above principles is testing or inspection of the final product to guarantee the standards described in #3 above and the hazard control procedures described in #4 above are actually ensuring food safety. That is the fundamental difference of a HACCP-based system. The key assumption of HACCP is that if the process is working properly, and the process has been designed based on a “sound scientific process,”¹⁹² then the end product is considered safe for the consumer.¹⁹³

As mentioned above, HACCP is not a new concept, and though these principles were identified and established approximately thirty years ago, they have been put in practice in different forms for a much longer time. Just in the shellfish safety context, HACCP principles were actually applied to the danger that was the very source of the creation of the National Shellfish Sanitation Program in 1925. In order to combat the typhoid outbreak that caused a massive shellfish scare in 1924 and 1925, some HACCP-type principles were applied to the problem.¹⁹⁴ More closely related to the current HACCP principles, however, is the system for preventing botulism in low-acid canned foods. In fact, the danger of botulism in low-acid foods was the first area of food safety risk to which HACCP principles were directly applied.¹⁹⁵ Seafood is, however, the first sector of the food market in which HACCP principles have been applied to the entire sector for all health and safety risks.¹⁹⁶

¹⁹¹*FDA Backgrounder 2*

¹⁹²*FDA Backgrounder 2*

¹⁹³27-233

¹⁹⁴27-227 Shellfish-related typhoid incidents have practically disappeared, though whether as a result of these principles is unknown.

¹⁹⁵Remarks by David Kessler, January 21, 1994, *available online at <http://www.fda.gov/bbs/topics/SPEECH/SPE00048.htm>* (According to then-Commissioner Kessler, the HACCP system was applied to low-acid foods to control the risk of botulism in the late 1970's.).

¹⁹⁶27-251

The first modern effort to apply HACCP principles to the seafood industry began in the late-1980s. At the time, as has been discussed above, the safety of the American seafood supply was being seriously called into question.¹⁹⁷ The FDA, acknowledging its efforts had not maintained consumer confidence in seafood safety, embarked upon a project to update its seafood regulations with HACCP principles.¹⁹⁸ Actually, the very first HACCP-based program in the seafood industry was run by the National Marine Fisheries Service. The Model Seafood Surveillance Project, run as a voluntary, cooperative effort between the states and industry under the NMFS, started in 1987 and identified HACCP-based approaches for the majority of the seafood and shellfish industry.¹⁹⁹ After that project was completed, the NMFS began work with the FDA on developing a comprehensive, voluntary HACCP program that would encompass every aspect of the entire industry from harvest to consumption.²⁰⁰ This water-to-table HACCP approach was first put into effect in 1992 after almost three years in development and became part of the NMFS Voluntary Seafood Inspection Program.²⁰¹ Based on the progress of this program and a worldwide movement toward HACCP principles in food inspection that required American exporters to adopt such programs or suffer in international markets, the FDA began in 1991 studying the feasibility of mandatory HACCP safety controls for the entire seafood and shellfish industry.²⁰²

By 1994, the FDA had progressed to the point of being ready to issue proposed regulations for the entire seafood and shellfish industry relying on HACCP principles. The proposed rules were issued on January 28, 1994, under the title: *Proposal To Establish Procedures for the Safe Processing and Importing of Fish and Fishery Products*.²⁰³ The FDA provided in this proposal, and reaffirmed in the final rule, the reasons supporting the creation of this new system of seafood regulation. The five bases for the mandatory HACCP

¹⁹⁷ See *supra* notes XXXXX and accompanying text.

¹⁹⁸ 27-251

¹⁹⁹ 27-251 & 27-267

²⁰⁰ 27-267

²⁰¹ 27-268 For more detail on the Voluntary Seafood Inspection Program, see *infra* notes XXXXX and accompanying text.

²⁰² 27-251

²⁰³ 59 Fed Reg 4142

safety controls included:

1)

To create a more effective and efficient system for ensuring the safety of seafood than currently exists;

2) To enhance consumer confidence;

3) To take advantage of developmental work on the application of HACCP-type preventive controls for seafood (e.g. the NMFS trials)....

4) To respond to requests by seafood industry representatives that the Federal government institute a mandatory, HACCP-type inspection system for their products; and

5) To provide U.S. seafood with continued access to world markets, where BHACCP-type controls are increasingly becoming the norm.²⁰⁴

The FDA also offered the additional explanation that seafood was distinct from almost all other food and offered unique regulatory challenges given that it is still predominantly wild caught and harvested.²⁰⁵ The FDA called the traditional inspection system a failure. It cited as a basis for this conclusion both the inability of inspections to reduce safety hazards in the seafood industry and the diminishing public confidence in the safety and wholesomeness of the commercial seafood supply.²⁰⁶ HACCP principles were particularly well suited to the regulation of this industry according to the FDA. “To ensure safety, it is of utmost importance that those who handle and process seafood commercially understand the hazards associated with (specific types of seafood with which they are involved), and keep these hazards from occurring through a routine

²⁰⁴60 Fed Reg 65096, at 65097

²⁰⁵60 Fed Reg 65098

²⁰⁶60 Fed Reg 65098

system of preventive controls.”²⁰⁷

Finally, the FDA addressed issues of international compliance facing American seafood exporters. Though it acknowledged that international trade was not a public health issue, it addressed concerns in this area as a major consideration when considering the costs and benefits of a regulatory system.²⁰⁸ HACCP principles were a desirable basis for regulation in large part because of the adoption of those systems for international use by the Codex Alimentarius Commission and the growing number of international markets requiring HACCP-type controls, such as the European Union.²⁰⁹

The specific regulations put forth in 1994 are neither detailed nor complex. In less than five pages, they basically adopt the broad principles of HACCP and apply them to all seafood and shellfish handlers and processors.²¹⁰ Industry participants are required to list food safety hazards, list critical control points, list critical limits on these hazards, list monitoring procedures, include program monitoring procedures and system verification procedures, and provide for a record keeping system that documents the above.²¹¹

The one exception to this abstract level of generality was in the regulation of raw shellfish. The FDA issued an additional subpart to the regulations specifically addressing raw shellfish processing.²¹² In doing so, it cited as support for this regulatory addition the fact that raw shellfish cause the overwhelming majority of all seafood-related illnesses.²¹³ The regulations for shellfish processors set forth a series of requirements applying only to these industry members and in addition to the rest of the HACCP requirements for all seafood handlers and processors. The regulations, entitled Subpart C, set rules for indicating the efforts made to control the origin of shellfish processed by these industry participants.²¹⁴ The regulations stated that processors were required to: 1) “only process molluscan shellfish harvested from growing waters ap-

²⁰⁷60 Fed Reg 65097

²⁰⁸60 Fed Reg 65098

²⁰⁹60 Fed Reg 65098

²¹⁰27-252

²¹¹21 CFR 123.6

²¹²21 CFR 123.28

²¹³60 Fed Reg 65163

²¹⁴21 CFR 123.28

proved for harvesting by a shellfish control authority”; 2) “accept only shellstock from a harvester that is in compliance with such licensure requirements as may apply to the harvesting of molluscan shellfish”; 3) “accept only containers of shucked molluscan shellfish that bear a label (indicating date, location of harvest and quantity of shellfish).”²¹⁵

Though the regulations still left the majority of details of shellfish supervision to the states (as with designation of approved growing waters), this added section marked a huge step in the regulation of shellfish processing. This was the first regulation specifically tailored to the shellfish industry giving the FDA the power to regulate and supervise the interstate market. This regulation came with actual enforcement consequences for failure to comply. Most importantly, the regulations stated that, “failure of a processor to have and implement a HACCP plan that complies with this section...shall render the (seafood) of that processor adulterated...”²¹⁶ Whereas prior to this regulation, the FDA had the power only to decertify state shellfish sanitation programs and no enforcement power against individual industry participants (as indicated *supra* with regard to FDA supervision of the NSSP), these provisions gave the FDA the ability to take action against non-complying processors and handlers as well as their product.²¹⁷ The FDA provided as the basis for this unprecedented increase in enforcement authority, with regard to shellfish, one proposed and ultimately rejected twenty years earlier, the continued failure of state and federal voluntary inspection programs to ensure the safety of the shellfish supply—specifically by ensuring harvesting only from safe, uncontaminated growing waters:

²¹⁵21 CFR 123.28

²¹⁶21 CFR 123.6

²¹⁷60 Fed Reg 65164

FDA recognizes that while States are making significant and important efforts to ensure that all shellfish harvested in their jurisdiction are taken only from open waters and then properly tagged, some shellfish that do not meet these requirements inevitably escape State control. The new provisions will allow FDA to take action against shellfish that are not harvested from open waters or that are not properly tagged if it encounters such shellfish in interstate commerce and make the gravamen of such action the origination from unopen waters or the lack of proper tagging itself, rather than evidence that the shellfish are injurious to health.²¹⁸

Though the final rule was published in 1995, the actual requirement of a HACCP program by every processor did not take effect until 1997.²¹⁹ During that grace period, processors were expected to develop HACCP plans that would be in accordance with the broad, general requirements of the new regulations. The FDA recognized the difficulty businesses might have in identifying, evaluating and combating safety hazards that could occur before, during, and after their handling and processing activities. In order to provide guidance to firms in developing and implementing HACCP safety plans, the FDA published the Fish and Fishery Products Hazards and Controls Guide as a supplement to the regulations.²²⁰ This guide was advisory and nonbonding, however, the FDA made clear that its future enforcement actions would be “consistent with the policies reflected in the guidance.”²²¹ The guide provided a start-to-finish hazard analysis along with critical control points at which these hazards could be eliminated or contained, in effect providing industry participants with a model HACCP outline upon which to tailor their own plans.²²²

Evaluating the HACCP Program 5 Years In

²¹⁹27-254

²²⁰Fish and Fishery Products Hazards and Controls Guide (draft) February 16, 1994.

²²¹Guide 6

²²²Guide

As noted above, the 1995 regulations were the first time the FDA had instituted a HACCP-based program for an entire sector of the food industry. Though the principles underlying HACCP had been in existence for three decades and had been evaluated and tested in numerous federal studies and academic analyses as well as through implementation in smaller trial programs, the industry-wide program itself had no proven track record and was very much an experiment in modern regulation. In fact, the FDA recognized this and considered the need for evaluation of the program one of the most serious post-implementation challenges for the HACCP safety control system.

Even prior to final implementation of the mandatory requirements, the FDA was already struggling with finding means of evaluating the results. As Dr. Michael Friedman, the Deputy Commissioner for Operations at the FDA testified to Congress in 1996, “(h)ow to evaluate the effectiveness and worth of the mandatory HACCP program for seafood raises issues that have not fully been solved.”²²³ Dr. Friedman conceded that consumer confidence in seafood safety, for instance, would not likely improve solely because a new regulatory regime had been put in place. Additionally, he cited as the single “most relevant accomplishment” he hoped to be achieved by the program would be “a measurable decrease in seafood-borne illnesses.”²²⁴ Beyond this measure, determining the effectiveness of the HACCP system in the short term may primarily mean judging the level of compliance by industry with the imposed requirements. This indication would demonstrate whether the regulations themselves were actually being implemented at the level of individual processors. The effectiveness of the control programs adopted, however, might ultimately only be measurable through longer-term examinations of seafood health risks and seafood-related illnesses.

²²³27-255

²²⁴27-255

The GAO set out in 2000 to evaluate the effectiveness of federal seafood regulation. It published its results in two separate reports distinguishing between all seafood other than shellfish and shellfish (oysters, clams, mussels, and scallops). Perhaps giving away the results, the two reports, published in January and July of 2001, were entitled: Federal Oversight of Seafood Does Not Sufficiently Protect Consumers and Federal Oversight of Shellfish Safety Needs Improvement.²²⁵ Both reports focused on the FDA's role under the new HACCP requirements, with the shellfish report also analyzing federal involvement in the ISSC. The two reports are dealt with separately below.

Report on the Regulation of the (non-Shellfish) Seafood Industry

The GAO identified a series of problems that have prevented HACCP regulations from achieving the safety assurance goals intended. Most striking was the fact that, although the regulations took effect in 1997 and industry had been provided a two-year grace period to prepare for the mandatory system, the percentage of firms complying with the requirements of the system by 1999 had still only reached 44%.²²⁶ Despite the fact this statistic indicates noncompliance by a majority of the industry, the FDA had actually made significant progress in this area, raising the figure from 32% in 1998.²²⁷ Aside from initial gaps in implementation that might be eliminated over time as the system becomes more familiar to the industry, the GAO identified four major weaknesses of the current regulatory regime that require correction if program effectiveness is to be improved.

First, despite the fact that HACCP requirements were intended to be universal, a large portion of the industry either is not participating or is exempt from the requirements. The FDA does not have a system of identifying seafood processors and thus cannot determine the level of participation. Though the FDA

²²⁵GAO Reports January and July, 2001 (Sources 3 and 4)

²²⁶January Report 5

²²⁷Jan Rep. 5

has identified almost 4,000 seafood processors, the GAO concluded that the actual number is likely much higher.²²⁸ The level of compliance at these firms cannot be determined, quite simply, because the FDA is not aware of their existence. Additionally, the FDA has exempted a large number of seafood processors involved in interstate commerce. Commercial fishing vessels that engage in some level of processing of their catch are excluded from the definition of “processor” under the HACCP requirements.²²⁹ The FDA rationale for this exemption is practical in nature: the commercial fishing fleet is so large that it would overwhelm the system if these were subject to HACCP requirements and FDA inspection.²³⁰ Finally, though almost all products possess risks for which HACCP procedures could be established, the FDA exempts those products that pose risks not reasonably likely to occur. This exemption has led to 30% of all seafood products not being subjected to HACCP plan requirements.²³¹ The GAO contrasted this situation with USDA requirements for meat and poultry processors where all products must be included in a processor’s HACCP plan.²³²

Second, the GAO criticized FDA monitoring of HACCP compliance by firms covered by the system. Almost one-half of all inspections performed by the FDA are little more than paperwork reviews whereas full inspections, according to agency policy, are supposed to focus on in-plant observation of actual product processing.²³³ Even for the quantity and quality of inspections that did occur, compliance is remarkably low. 22% of products for which a HACCP plan is required had none in 1999, and more than half of the HACCP plans that did exist contained “serious deficiencies”.²³⁴ The GAO evaluated serious deficiencies based on FDA compliance manual standards based almost entirely on the seven HACCP principles.²³⁵ The six types of serious deficiencies are: 1) not identifying serious health and safety hazards; 2) not identifying a critical control point for each hazard; 3) not identifying a critical limit for the control point; 4) not identify-

²²⁸Jan Rep 14

²²⁹Jan Rep 14

²³⁰Jan Rep 15

²³¹Jan Rep 16

²³²Jan Rep 16 The USDA HACCP program was established on January 30, 1998.

²³³Jan Rep 17

²³⁴Jan Rep 18

²³⁵See *supra* notes XXXXX and accompanying text.

ing appropriate monitoring procedures; 5) not identifying record keeping procedures; and 6) not identifying adequate corrective action procedures when monitoring identified failures of the system.²³⁶ The GAO cited a further weakness in the HACCP requirements in that one specific health risk is not addressed even in plans that meet FDA guidelines. The FDA has established no HACCP requirement for methyl mercury despite the fact the substance is highly toxic and has recently been identified in dangerous levels in some popular types of seafood.²³⁷ This omission, according to the GAO, leaves even complying HACCP programs incomplete in addressing health and safety risks for several seafood species.

FDA response to HACCP regulation violations is also not effective. The principal means of addressing violations identified in plant inspections is the warning letter; however, the GAO noted that 94% of warning letters are delayed beyond the recommended issuance timelines with the time between receipt of warning letter recommendations and approval of the final letters averaging 73 days.²³⁸ This failure by the FDA to provide timely notice of regulatory violations is most significant because 67% of all warning letters issued are for what are considered serious health risks, such as Scromboid Poisoning.²³⁹ The FDA response is that warning letters have to pass through a review process that leads 95% of all letters to be rewritten before final approval.²⁴⁰

The third major weakness of the HACCP plan is significant because it demonstrates the potential gap between HACCP compliance and actual risk reduction. According to the GAO, the FDA is proceeding with HACCP on little more than a presumption that full implementation will actually result in a decrease in the number of seafood-related illnesses.²⁴¹ In contrast, the USDA determined salmonella levels in meat and poultry before implementation of its HACCP requirements in order to be able to measure the effectiveness

²³⁶ Jan Rep 18

²³⁷ Jan Rep 20

²³⁸ Jan Rep 21

²³⁹ Jan Rep 21

²⁴⁰ Jan Rep 22

²⁴¹ Jan Rep 22

of the HACCP program in reducing that health risk.²⁴² The FDA responded that the wide variety of health risks in seafood differs greatly from the relatively small number of significant risks in meat and poultry, making end result measurements less feasible, but the fact that many health risks that account for the overwhelming majority of seafood illnesses, such as Ciguatoxin and Scromboid Poisoning, are species-specific makes this counter less convincing.

Finally, the FDA is not able to adequately ensure the level of HACCP compliance by imported seafood processors. As noted above, imports account for approximately 60% of the entire seafood market, so imports are no small concern. Yet, the FDA has very limited capacity to evaluate the safety control measures applied by processors in other countries or to determine the safety of imported products. The GAO noted two major obstacles to compliance measurement. First, the FDA has not yet developed equivalence agreements with any importer country, though these agreements, which establish the equivalence of those countries' processes with HACCP requirements, are the simplest and most effective means of ensuring compliance.²⁴³ In the absence of equivalence agreements, the FDA must establish the compliance of each importer firm, yet the FDA concedes that less than one-third of all importers can provide documentation or otherwise demonstrate that its procedures comply with HACCP requirements.²⁴⁴ Finally, the FDA is not able to engage in inspections at the port of entry such that product safety can be determined. Less than 1% of all imports are subject to any kind of laboratory inspection and only 3% even receive a visual inspection.²⁴⁵

The GAO outlined the following recommended actions by the FDA in order to improve the effectiveness of its seafood HACCP program:

1.

²⁴² Jan Rep 22

²⁴³ Jan Rep 23

²⁴⁴ Jan Rep 23

²⁴⁵ Jan Rep 32

Require compliance by all processors including fishing vessels- this includes adoption of a relatively inexpensive system of requiring registration of all processors engaged in interstate commerce so that HACCP inspections can take place;

2. Conduct in-depth audits of all existing HACCP systems to determine compliance;
3. Emphasize actual product processing observation during inspections;
4. Get serious about the methyl mercury risk by moving beyond consumer advisories and establishing recommended HACCP control procedures;
5. Issue warning letters to violators on a timely basis;
6. Assess the effectiveness of HACCP systems in reducing health risks and occurrence of seafood-related illnesses;
7. Develop equivalence agreements and possibly require them for all importing countries (this would necessitate Congress amending the Federal Food Drug and Cosmetic Act);
8. Develop effective port of entry inspections to prevent dangerous products from reaching American markets.²⁴⁶

In sum, the FDA did not disagree with most of these recommendations except in that it did not think requiring fishing vessels to comply with HACCP requirements would be either feasible or desirable.²⁴⁷ The FDA also cited a need for significantly increased funding to resolve most of the problems illustrated in this report.²⁴⁸

²⁴⁶ Jan Rep 34-35

²⁴⁷ Jan Rep 36

²⁴⁸ Jan Rep 6

Report on the Regulation of the Shellfish Industry

The GAO evaluation of the FDA's shellfish supervision included evaluation of cooperative efforts with the ISSC and administration of the NSSP. Particular attention was directed towards *Vibrio Vulnificus* risks as that continues to be the deadliest shellfish-related health risk. Most shellfish regulation is still at the state level and is essentially voluntary under the ISSC and NSSP, however 1997 did change circumstances somewhat with the application of HACCP requirements to all shellfish processors.²⁴⁹ Additionally, the NSSP has incorporated HACCP principles into its requirements for all participating states.²⁵⁰

Significantly, *Vulnificus* is not treated as a hazard to be identified or controlled for under HACCP plans.²⁵¹ The FDA and ISSC provide several reasons for the exclusion of *Vulnificus* from its HACCP requirements, though upon examination, those justifications may not stand up to direct scrutiny. The first reason *Vulnificus* is not classified as a health hazard is that it occurs naturally in shellfish.²⁵² That reasoning does not seem to make sense given health hazard designation of other natural seafood safety risks such as scrombotoxin and ciguatoxin. The FDA and ISSC provide not basis for this distinction, though it is possible that the universality of contamination, particularly of Gulf Oysters, may influence this decision. Further, regulators cite uncertainty about the level of contamination necessary to cause illness.²⁵³ Again, this justification does not seem to provide a distinction from other hazards covered under HACCP, such as many chemical contaminants, for which the precise level of exposure that poses a health threat is unknown. Still, *Vulnificus* is exempt from HACCP requirements and is thus treated separately in this report.

²⁴⁹ See *supra* notes XXXXX and accompanying text.

²⁵⁰ July Rep 3

²⁵¹ July Rep 3

²⁵² July Rep 3

²⁵³ July Rep 3

The GAO identified three primary failures of FDA oversight of the NSSP. These track somewhat similarly to the failures of non-shellfish regulation. The distinction lies in the fact that the FDA's role in shellfish safety is much more one of supervision and coordination rather than direct inspection, which is primarily left to the states under the NSSP.

First, the FDA does engage in risk-assessment to determine resource allocation.²⁵⁴ Though the FDA concedes it has limited resources available to engage in program monitoring and review, it has no way of allocating its resources in a manner that can efficiently address the most serious health and safety risks. Instead, the FDA basically expends equal resources monitoring each NSSP-participating state. As an example of the weakness of this approach, the GAO pointed out that the FDA spent basically the same amount of money evaluating the Delaware shellfish program as it did the Louisiana shellfish program despite the fact Delaware produces far less shellfish for interstate commerce than Louisiana and Louisiana has been the source of a much higher number of shellfish-related illnesses.²⁵⁵ Additionally, the FDA does not base future resource allocation on demonstrated risks and past program deficiencies. Despite the fact four state programs were seriously in violation of NSSP requirements in 1999, the FDA allocation of resources for these states did not differ from that of other states that had been in substantial compliance with program requirements.²⁵⁶

The GAO also reported that the FDA is also failing in its information-gathering responsibilities. The FDA does not compile state compliance statistics though it acknowledges that many states are neither identifying contaminated growing waters nor preventing illegal harvesting (two problems cited repeatedly throughout the 1970's and 1980's).²⁵⁷

As with non-shellfish HACCP regulations, the FDA does not have measurable standards of safety risks by which it can determine the effectiveness of HACCP controls in reducing shellfish-related illnesses.²⁵⁸ Be-

²⁵⁴July Rep 8

²⁵⁵July Rep 9

²⁵⁶July Rep 9-10

²⁵⁷July Rep 10

²⁵⁸July Rep 11

cause of this, the FDA cannot evaluate progress or lack thereof nor can it compare state programs to identify successful approaches to shellfish safety. The FDA responds that it has not been able to identify reliable and effective means of measuring bacterial reductions and shellfish-related illnesses, and that, until those two measures are possible, the safety benefits of HACCP controls and other programs cannot be determined.²⁵⁹ With regard to *Vibrio Vulnificus*, since HACCP programs are not required to address this risk, the GAO evaluated ISSC efforts to combat illness caused by the bacteria. The GAO concluded that the ISSC has been unable to reduce risks associated with *Vulnificus*.²⁶⁰ This determination is based on the fact that, despite six years of efforts directed specifically against this single risk, the number of related illnesses and deaths has remained constant.²⁶¹

The ISSC has established a goal of reducing illnesses and deaths caused by *Vulnificus* by 60% by 2008, but the GAO concluded it is unlikely that the ISSC will meet this level of reduction.²⁶² In the event the ISSC has not met the goal, states will be required to take further steps to address the problem, and these could have a significant economic impact on the shellfish industry. To date, the ISSC has focused almost exclusively on consumer education as a means of reducing *Vulnificus*-related illnesses.²⁶³ The NSSP has also adopted refrigeration requirements, and the GAO concludes that these could have been effective; however, the requirements were relaxed due to industry concerns about the economic burden they would have placed on harvesters.²⁶⁴ The result has been no impact on the safety risks posed by *Vulnificus*-related illnesses.

The GAO presented two general options available to reduce *Vulnificus*-related illnesses and meet the 60% reduction goals. The first of these options is that of immediate refrigeration requirements.²⁶⁵ This option, however, is unlikely to be adopted because of the substantial economic costs to harvesters, who are typically

²⁵⁹July Rep 11

²⁶⁰July Rep 12

²⁶¹July Rep 12

²⁶²July Rep 12

²⁶³July Rep 13-14

²⁶⁴July Rep 12-13

²⁶⁵July Rep 17-18

smaller operators unable to comply with such requirements. The second option is to require post-harvest treatment. There are three types of post-harvest treatment available: hydrostatic pressure; “cool pasteurization”; and quick freezing.²⁶⁶ In contrast to refrigeration, these approaches are considered cost effective for processors. In fact, studies have indicated that both hydrostatic pressure and cool pasteurization could actually increase revenues for processors by reducing the cost of producing shucked oysters and increasing the price consumers are willing to pay for treated, half shell oysters.²⁶⁷ The one disadvantage noted for post-harvest treatments is that some consumers, for taste and aesthetic reasons, would prefer untreated oysters yet that option could be driven from the market by such requirements.²⁶⁸

Ultimately, the GAO made a series of recommendations for improving shellfish regulation and state supervision. Based on these recommendations:

1.

FDA should adopt a risk-based approach to resource allocation;

2. FDA should create a standardized, automated system of compiling state program data and comparing state programs;

3. FDA should perform baseline testing to establish the effectiveness of HACCP controls and NSSP requirements in reducing safety risks and shellfish-related illnesses;

4. ISSC should develop a post-harvest treatment system to reduce the *Vulnificus*-related illness risk.²⁶⁹

The FDA essentially agreed with the recommendations of the GAO, but the ISSC disputed two assertions

²⁶⁶ July Rep 18

²⁶⁷ July Rep 18

²⁶⁸ July Rep 18

²⁶⁹ July Rep 19

in the report. It rejected generally accepted estimates that shellfish cause approximately 85-90% of all seafood-related illnesses (100,000 per year), and it maintained the anticipated effectiveness of its programs in combating *Vibrio*-related illnesses, rejecting any need for additional measures at this time.²⁷⁰

National Marine Fisheries Service

The FDA regulatory regime is the dominant yet not the only major federal oversight program for the seafood industry. The National Marine Fisheries Service maintains its own program for seafood inspection. This program is neither mandatory nor comprehensive and its focus is on plant inspection rather than seafood health risks. Still, the program is an important aspect of the current status of seafood regulation.

The Voluntary Seafood Inspection Program (VSIP) was established in 1946 as part of the Agricultural Marketing Act.²⁷¹ The program is primarily a fee-for-service plant inspection service with the goal that “(seafood) products may be marketed to the best advantage, that trading may be facilitated, and that consumers may be able to obtain the quality product which they desire.”²⁷² As mentioned above, HACCP-based inspections were incorporated into the program in 1992 before the FDA issued its mandatory HACCP requirements. The VSIP continues to offer HACCP-based plant inspection as part of its services.

Along with its plant inspection program, the NMFS offers the only seafood grading marks of any federal program. Participants in the VSIP can obtain a U.S. Grade A, B or C mark on their product as well as the P.U.F.I. stamp which certifies that the product was “Produced Under Federal Inspection.”²⁷³ Despite

²⁷⁰July Rep 21

²⁷¹Book 300

²⁷²27-259 & 260, quoting Ag. Marketing Act

²⁷³Book 300

the apparent marketing advantage one would assume federally graded and certified seafood products would have, especially given continuing consumer concerns about seafood safety, the VSIP has never really covered a large percentage of the overall seafood market. As of 1996, the program only reached about 8% of the entire seafood industry.²⁷⁴ Often cited as a primary obstacle to more widespread coverage is the fee-for-service nature of the program. The current price schedule for the program charges approximately \$55 per hour for inspection services.²⁷⁵ In 1998, it was proposed that the program be moved from the NMFS to the FDA, and the same proposal has been made in each of the following years; however, for now, the program continues to reside in the National Marine Fisheries Service.

²⁷⁴27-274

²⁷⁵Seafood Inspection Program Fees, *available online at* <http://seafood.nmfs.noaa.gov/Fees2002.htm>